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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/156,367 09/17/98 LIU Y YFL98-01PA

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HM12/0703

EXAMINER

ALLEN, M

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 07/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.
09/156,367

Applicant(s)

Liu

Examiner

Marianne P. Allen

Group Art Unit

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☒ Responsive to communication(s) filed on Apr 10, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-25, 27-32, and 44 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-25, 27-32, and 44 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1630, Art Unit 1631.

Claims 26 and 33-43 have been cancelled and claim 44 has been newly added. Claims 1-25, 27-32, and 44 are under consideration by the examiner.

Applicant's arguments filed 4/10/00 have been fully considered but they are not persuasive or are moot in view of the new ground(s) of rejection.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant is being given benefit to the instant filing date (9/17/98) and being denied benefit to the provisional application filing date (5/14/98). As presently written, the full scope embraced by each claim was not disclosed in the provisional application. The methods as claimed were not disclosed in the provisional application. The provisional application is essentially a research paper and discloses particular experiments performed. There is no generic disclosure of the methods as presently claimed.

The declaration under 37 CFR 1.132 filed 4/10/00 is sufficient to overcome the rejection of claims 1-2, 4, 6, 8-9, 11, 13-15, and 17 based upon 35 U.S.C. 102(a) as being anticipated by

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Liu et al. (Society for Neuroscience Abstracts, October 1997) and claims 9-10, 14, and 18 based upon 35 U.S.C. 103(a) as being unpatentable over Liu et al.

The rejection of claims 1-2, 5-9, 12-16, and 19-32 under 35 U.S.C. 103(a) as being unpatentable over the combination of Yardin et al. (Neuroreport, 22 June 1998), Ni et al. (U.S. Patent No. 5,840,509), and Johnson (U.S. Patent No. 5,854,043) is withdrawn in view of the amendments to the claims.

The rejection of claims 1-2, 5-7, 9, 12, 14-16, 19-22, and 24-32 under 35 U.S.C. 103(a) as being unpatentable over the combination of Cheung et al. (Journal of Neuroscience Research, 1 April 1998), Ni et al. (U.S. Patent No. 5,840,509), and Johnson (U.S. Patent No. 5,854,043) is withdrawn in view of the amendments to the claims.

Claims 1-25, 27-32, and 44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the methods as outlined below, does not reasonably provide enablement for the breadth of the claims as written. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1 and 9 are directed to methods for assessing a compound's ability to prevent neuronal cell death occurring in a mammal susceptible to or having a neurological condition.

Claim 14 is directed to a method for assessing the ability of an MLK inhibitor to prevent neuronal cell death occurring in a mammal susceptible to or having a neurological condition.

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Claim 19 is directed to a method for screening a compound's ability to inhibit MLK activity and thereby prevent neuronal cell death occurring in a mammal susceptible to or having a neurological condition.

Claim 24 is directed a method for assessing a compound's ability to inhibit MLK activity and thereby prevent neuronal cell death occurring in a mammal susceptible to or having a neurological condition.

Claim 29 is directed a method for assessing a compound's ability to inhibit MLK kinase activity and thereby prevent neuronal cell death occurring in a mammal susceptible to or having a neurological condition.

While the preambles of the claims concern neuronal cell death in a mammal, the specification does not describe nor enable performing the claimed methods in an intact mammal. That is, the exemplified methods are performed on isolated cells in culture or in vitro. These cell culture and in vitro methods appear to be what was intended (note that the claims do not recite administering compounds to a mammal); however, further consideration of the claim language does not preclude performing the method in a mammal. Furthermore, assuming that the cell culture and in vitro methods were what was intended to be claimed, the method steps performed do not address the intention of evaluating the compound's activity in the mammal in question. For example, the steps of claim 1 require contacting a compound with neuronal cells having activated MLK activity and determining the number of neuronal cells that die. The neuronal cells do not have to be mammalian nor do they have to be from a mammal susceptible to or having a

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neurological condition. That is, the method as written only identifies compound that inhibit (not necessarily prevent as set forth in the preamble) neuronal cell death but does not correlate or further test that inhibiting activity in vivo. Thus, claim 8, for example, identifies the particular condition as being Alzheimer's or Huntington's disease yet the method steps do nothing to discriminate compounds useful for these diseases versus any other encompassed by the claim.

The claims recite "MLK inhibitor," "activated MLK activity," "MLK protein" and so forth. The specification does not appear to specifically define the metes and bounds of the intended activities, proteins, and activities. The definitions on page 12, lines 20-25, are somewhat circular and open-ended. While specific MLK's are identified (see pages 2-3, bridging paragraph, and page 10, lines 11-15) and particular MLK activities (apoptosis, kinase activity) are disclosed, reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not describe nor enable identification of any other MLK proteins or activities meeting the functional limitations of the claims and it is deemed to constitute undue experimentation to determine them. The enablement of the claims can be viewed similarly to those in Ex parte Maizel, 27 USPQ2d 1662, 1665. The Board of Patent Appeals and Interferences held that claims drawn to DNA sequences encoding biologically equivalent proteins (i.e. DNA encoding proteins that do not have a defined amino acid sequence) are not enabled when the specification discloses a single specific DNA sequence known to the inventor having the biological limitations. The disclosure was held not to be commensurate in scope with the breadth of such claims because DNA sequences encoding biologically equivalent proteins covers any


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DNA sequence encoding a protein which achieves the stated biological result. Note that most of the present claims lack any structural or specific activity limitation for the MLK. It is further noted that the specification states on page 10 that MLK1, MLK2, and MLK3 are the only kinases known to directly activate the SEK1-JNK cascade and that MLK2 is the neuronal form. As such, it appears that the specification enables only MLK2 and those biological activities specifically associated with MLK2 for use in the present methods. The specification fails to provide sufficient further guidance for identifying MLK proteins, inhibitors, or activities. As such, applicant's specification is an invitation to experiment analogous to that in Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1001, 1005, which was not deemed to be enabling. "It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 9:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028. Official FAX communications may be directed to either (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


MARIANNE P. ALLEN
PRIMARY EXAMINER
~~GROUP 1631~~
44/1631